Doc Code: AP.PRE.REQ

PTO/SB/33 (12-08)
Approved for use through 01/31/2009. OMB 0651-00xx
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)
01-202

Certificate of Electronic Transmission
Under 37 C.F.R. §1.8

I hereby certify that this correspondence and any document referenced herein are being electronically filed with the USPTO via EFS-Web on October 13, 2009.

Nancy Joyce Simmons
(Printed Name of Person Sending Correspondence)

/nancy joyce simmons/
(Signature)

Application Number	Filed
10/075,970	February 14, 2002

First Named Inventor
Michael Helmus

Art Unit	Examiner
3773	Melanie Ruano Tyson

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- [ ] applicant /inventor.
- [ ] assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- [x] attorney or agent of record. Registration number 29,674
- [ ] attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34.

/Rosemary M. Miano/
Signature

Rosemary M. Miano
Typed or printed name

908.518.7700
Telephone number

October 12, 2009
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

[x] *Total of 1 forms are submitted.

REASONS FOR REQUESTING PRE-APPEAL REVIEW

1) Status of Claims

Claims 1, 3, 5-7, 9-21 and 46-50 are pending in this application. Claims 2, 4, 8 and 22-45 have been canceled. Thus, Claims 1, 3, 5-7, 9-21 and 46-50 are presented for review.

2) The Rejection Under 35 U.S.C. § 103(a) Based HOGANSON in View of BOLZ is Erroneous

Claims 1, 3, 5-7, 9-21 and 46-50 have been rejected under 35 U.S.C. 103(a) based on Hoganson et al., U.S. Application Publication No. 2003/0074049 ("HOGANSON") in view of U.S. Patent No. 6,287,332 ("BOLZ"). This rejection is in error.

Rejections based on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006), *cited with approval in KSR Int'l v. Teleflex, Inc.*, 127 S. Ct. 1727, 1740-41; 82 U.S.P.Q. 1385, 1396 (2007). As explained below, none of the references alone or in combination provides any reason or suggestion to combine the references to arrive at the present invention. *In re Nilssen*, 851 F2d 1401, 1403; 7 U.S.P.Q.2d 1500, 1502 (Fed. Cir. 1988).

HOGANSON describes:

> A covered stent for use in a vessel, duct, lumen or hollow organ of a living being. The covered stent includes a stent or framework of interconnected elongated members in the form of a hollow tube having an inner surface and an outer surface. The stent may be a coiled stent, slotted tube stent, self-expanding stent, or any other intravascular stent design and may be metal or a polymer or a combination. A cover is disposed over a portion of the stent, either on the inside surface, the outside surface or intermediate those surfaces. The cover may be a polymer and may be resorbable. The cover can be attached to the stent by wrapping a sheet of polymer material around the stent, or forming a tube of polymer material and mounting it over the stent. The cover can extend over the entire stent or only a portion of the stent and may include one or more drugs or other beneficial active agents for delivery into the body of the being. Moreover, the cover may have properties to prevent permanent occlusion of a side-branch or bifurcation when placed within a branching or bifurcated vessel and may be constructed to selectively perforate or otherwise provide an opening to allow flow in a side-branch or bifurcated vessel.

See Abstract.

It should be noted that there is a minor contradiction in HOGANSON as to the placement of a cover relative to the stent. The Abstract in HOGANSON states three alternatives, noting that "A cover is disposed over a portion of the stent, either on the inside surface, the outside surface or intermediate those surfaces." (Emphasis added.) The embodiments described in paragraphs 26-29 state four alternatives, reciting that "The cover is disposed over at least one of the surfaces of the hollow tubular framework (i.e., on the inside surface, the outside surface, or both) or within the interstices". (Emphasis added.) In either case, however, embodiments where the interstices are covered are an alternative to embodiments where the inner and/or

outer surfaces are covers. Thus, HOGANSON does not teach or suggest a biodegradable covering material completely covering an inner core material.

Note also that since HOGANSON a) uses sheet structures for its coverings (as explained below) and b) since there is no teaching or disclosure of how the stent could be covered "within the interstices" given this separate sheet structure, HOGANSON is not deemed to have enabled any such embodiment. Further, any covering of interstices alone is not a complete covering of an inner core. In the present invention, on the other hand, the covering material completely covers the biodegradable inner core material.

With regard to HOGANSON in general, this reference does not teach or disclose the present invention which provides:

> An implantable or insertable medical device adapted to provide a controlled change in mechanical properties and biomechanical compatibility after being implanted or inserted into a patient comprising a biodegradable inner core material and a biodegradable covering material completely covering the inner core material; wherein the biodegradable inner core material is selected from a metallic material and a ceramic material, wherein the covering material substantially controls the rate at which the inner core material becomes flexible upon contact with bodily fluids, wherein after insertion or implantation into a patient, the medical device becomes decreasingly rigid and increasingly biomechanically compatible with body tissue in contact with the device over time, wherein said biodegradable covering material does not contain therein a therapeutic agent, and wherein the medical device is substantially biodegradable by the body.

Claim 1 (the only independent claim presently pending) (emphasis added).

With regard to the concept of flexibility, HOGANSON describes the flexibility of its stents as follows: "The stent cover is preferably very flexible as to not impact the flexibility of the stent or overall stent system and for applications where the stent is to expand is preferably very plastic and/or elastic so it can expand as the stent is deployed." (See paragraph 134) (emphasis added).

Thus, in HOGANSON the stent cover starts off as being very flexible and is not used to control the rate at which the inner core material becomes flexible upon contact with bodily fluids. Indeed: 1) there is no modification in HOGANSON of the flexibility of a core material via a covering of an inner core over the period that the covering is contacted with bodily fluid; and 2) there is no description or suggestion in HOGANSON regarding the use of any covering to modify the flexibility of the medical device as described for the present invention; in fact, the cover preferably has no impact of the flexibility of the stent whatsoever.

HOGANSON uses exterior longitudinal structures in some embodiments of his invention. This concept is described at paragraph 82 as related to Fig. 3:

> In particular in FIG. 3 there is shown a covered stent 50 constructed similarly to stent 10, i.e., having a stent body or framework 20 but having a different cover 52. In this embodiment the cover 52 comprises three different materials 52a, 52b, and 52c mounted on the exterior surface of the stent 20 in respective longitudinally located sections of the cover. One or more materials can be used along the length of the cover to vary the mechanical or other properties of the cover. A cover material which is thinner or more elastic at the ends of the stent can allow the ends of the stent to expand first and provide a mechanical seal to prevent extrusion of the lesion out of the ends of the stent when the

> middle of the stent expands. Thus, the sections 52a and 52c can be made thinner than section 52b of the cover.

(Emphasis added.) However, the cover in HOGANSON is described as providing a mechanical seal not as providing any contribution to flexibility.

The approach taken by HOGANSON is not relevant to the present invention and, in fact, teaches away from complete coverage of the inner core material for the purpose of controlling the rate at which an inner core material becomes flexible upon contact with bodily fluids, instead preferring longitudinal structures on only the abluminal (vessel contacting) surface of the stent.

This is also the case with the paragraphs from HOGANSON cited by the Examiner in the Office Action of 7/1/09:

A) Paragraphs 70, 72, 78 and 85 of HOGANSON do not specifically describe any covering of the inner core of a stent which results in complete coverage of the inner core (i.e., outside surface, inside surface, and interstices) as is required by the present invention. Further, the element 22 of HOGANSON would not provide complete coverage as required by the present invention since element 22 is applied as a sheet and would not cover the additional surfaces (including the intermediate/interstitial surfaces), especially since the structures of HOGANSON are shown, for example, as slotted tubes and self-expanding stents.

B) The Examiner admits that HOGANSON also fails to disclose the biodegradable inner core material as being specifically selected from biodegradable metallic and ceramic materials. (Office Action 7/1/09, page 3).

The Examiner also discusses the hydrophobic surface erodible polymers as exemplified in Table 2 of HOGANSON as being "capable of controlling the rate at which the inner core material becomes flexible upon contact with bodily fluids." (Office Action 7/1/09, page 3). This concept is included in Claims 5 and 48-50 of the present invention which describes the inclusion of a hydrophobic surface erodible polymer as a covering material (Claim 5), and more particularly, the use of a polyamide, a polyorthoester or a polyanhydride as a covering material (Claims 48-50). There is no teaching or suggestion in HOGANSON, however, of using such materials to completely cover the inner core material as claimed, much less for purposes of modifying the flexibility of the medical device.

The Advisory Action, states that "the device itself (of Hoganson as modified by Bolz) would become decreasingly rigid as the covering and inner core material degrade over time" but this logic is flawed, *inter alia*, because:

1) BOLZ (further described below) does not contain any coating that is described as affecting flexibility.

2) The degradation of the cover described in HOGANSON (described as one which "can be attached to the stent by wrapping a sheet of polymer material around the stent, or forming a tube of polymer material and mounting it over the stent" (HOGANSON Abstract)) has not been demonstrated to have any

predictable effect on the flexibility of HOGANSON's device, much less by controlling the rate at which the inner core material becomes flexible upon contact with bodily fluids. Also, since BOLZ's structure has no polymer coating (only a protective oxide coating), BOLZ and HOGANSON are not combinable and the issue of any effect on flexibility based on a combination of HOGANSON and BOLZ is moot.

BOLZ describes: "An implantable, bioresorbable vessel wall support, in particular a coronary stent, comprises a combination of metal materials which dissolves in the human body without any harmful effects on the person that wears the implant. The combination of metal materials can be an alloy or a local galvanic element." (Abstract) (emphasis added). Thus, BOLZ teaches constructing a bioresorbable stent of degradable metallic materials. The only coating described in BOLZ is a protective oxide coat (see col. 2, lines 27-28). There is no teaching or suggestion of any polymer coating for any purpose in BOLZ at all and certainly no teaching of any coating which is taught as causing the device to become decreasingly rigid over time. Nor does BOLZ suggest that the coating described therein is deficient in any way. Thus, BOLZ is not combinable with HOGANSON.

BOLZ fails to teach or suggest a biodegradable covering material of any type that completely covers an inner core material as claimed in order to substantially control the rate at which the inner core material becomes flexible upon contact with bodily fluids. The protective oxide coat of BOLZ is merely designed to give uniform corrosion:

> For correspondingly uniform corrosion to be obtained, such an alloy comprises a component A which covers itself with a protective oxide coat. This component A is selected from one or several metals of the group of magnesium, titanium, zirconium, niobium, tantalum, zinc or silicon. For uniform dissolution of the mentioned oxide coat to be attained, a component B is added to the alloy, possessing sufficient solubility in blood or interstitial fluid, such as lithium sodium, potassium, calcium, iron or manganese.
>
> The mentioned elements are suitable because they are present in the human body anyway--such as magnesium, zinc, sodium, potassium, calcium, iron and manganese--or are know [sic] to be nontoxic--such as titanium, zirconium, niobium, tantalum, silicon and lithium. The combination of a passivating and a soluble component ensures a timely and uniform decomposition into biocompatible breakdown products. The corrosion rate can be regulated through the ratio of the two components.

(col. 2, lines 27-44) (emphasis added)

The Examiner also comments that for Claims 7, 10, 49 and 50, that it would be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. This, however, is a mere conclusory statement, without articulated reasoning with some rational underpinning to support the legal conclusion of obviousness, which is prohibited by *KSR* (see above).

Similarly, the Examiner's comments in the Office Action of 7/1/09, on Claims 11-14 and more generally in the Advisory Action include the statement that HOGANSON's failure to disclose that the inner core is a monofilament core or a multi-filament core comprising woven or braided filaments is overcome by

the argument that these would have been obvious choices as the structures described by HOGANSON. Again, the Examiner has failed to provide any logic for this assertion.

This is not the applicable standard:

> A statement that modifications of the prior art to meet the claimed invention would have been "'well within the ordinary skill of the art at the time the claimed invention was made'" because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993). **"'>[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396 quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006).

MPEP 2143 (emphasis added).

The Examiner has not met this standard, especially in view of the other features in the Claims as discussed above.

With regard to the Examiner's comments on Claims 15 and 19-21, it is respectfully submitted that these rejections are overcome for the reasons discussed above.

With regard to the Examiner's comments Claims 46 and 47, attention is again called to the lack of any teaching or suggestion in either or both of HOGANSON and BOLZ as discussed above concerning the use of a covering material to substantially control the rate at which an inner core material becomes flexible upon contact with bodily fluids, as described for the present invention.

For at least these reasons, Applicant respectfully submits that the rejections under 35 U.S.C § 103(a) are in error and Claims 1, 3, 5-7, 9-21 and 46-50 are patentable over the cited references.